II. REMARKS

Formal Matters

Claims 1-4 and 7-34 are pending after entry of the amendments set forth herein.

Claims 1, 7-9, 11, 12, 19, 20, 23, 24, and 26-29 were examined and were rejected. Claims 2-4, 10, 13-18, 21, 22, 25, and 30 were withdrawn from consideration.

New claims 31-34 are added. No new matter is introduced by new claims 31-34.

Applicants respectfully request reconsideration of the application in view of the remarks made herein.

Withdrawn rejections

Applicants note with gratitude that the following rejections, raised in the Office Action mailed December 20, 2006, have been withdrawn:

1) the rejection under 35 U.S.C. §101;
2) the rejection of claim 1 under 35 U.S.C. §112, second paragraph;
3) the rejection of claim 11 under 35 U.S.C. §112, second paragraph; and
4) the rejection of claims 1, 5-8, 11, 12, 19, 20, 23, 24, and 26-29 under 35 U.S.C. §102(b).

Claim objections

Claim 1 was objected to. The Office Action stated that claim 1 is objected to for reciting material drawn to non-elected inventions.

As noted previously, there is no requirement that Applicants delete non-elected species from a generic claim. As such, claim 1 need not be amended to delete reference to the non-elected species.

Rejections under 35 U.S.C.§112, first paragraph

Claim 9 was rejected under 35 U.S.C.§112, first paragraph, as allegedly lacking enablement. Claims 1, 7, 8, 11, 12, 19, 20, 23, 24, and 26-29 were rejected under 35 U.S.C.§112, first paragraph, as allegedly lacking adequate written description. Claims 1-4, 7, 8, 11, 12, 19, 20, 23, 24, and 26-29 were rejected under 35 U.S.C.§112, first paragraph, as allegedly lacking enablement.

Claim 9

The Office Action stated that the antibodies SWLA4 and SWLA5 are required in order to practice the invention; and stated that the deposit of biological organisms is considered by the Examiner to be necessary for the enablement of the current invention.

Without conceding as to the correctness of this rejection, Applicants note that the SWLA4 and SWLA5

hybridoma cell lines are being prepared for deposit. Once the SWLA4 and SWLA5 hybridoma cell lines are deposited, a Declaration Regarding Biological Deposit will be submitted.

Claims 1, 7, 8, 11, 12, 19, 20, 23, 24, and 26-29; written description

The Office Action stated that the claims are drawn to a genus of antibodies, the members of which recognize *Lactobacillus* species generally, and *Lactobacillus casei* specifically. The Office Action stated that Applicant has failed to fully characterize the antigen to which the claimed antibody binds. Applicants respectfully traverse the rejection.

The instant antibodies as claimed do not require any knowledge of a specific cell surface antigen on a cariogenic bacterium. All that is required is that the antibody bind specifically to a cell surface antigen on a cariogenic bacterium. As discussed in the instant specification, an antibody that binds specifically to a cariogenic bacterium, e.g., the antibody binds almost exclusively to the specific cariogenic bacterium and not to any other cariogenic bacterium. Specification, page 4, lines 10-31.

The instant specification describes making hybridomas to formalinized *A. naeslundii* (ATCC 12104) and *L. casei* (ATCC 11578). Specification, page 18, lines 28-29. The instant specification also describes use of an enzyme-linked immunosorbent assay (ELISA) for detecting hybridoma culture supernatants containing antibodies reactive with the corresponding bacteria. Specification, page 18, lines 30-33. The instant specification further describes how the antibodies were tested for cross-reactivity with a panel of bacteria shown in Table 1. Specification, page 19, lines 2-3; and Table 1, page 26. The instant specification then describes use of the antibodies to detect *A. naeslundii* or *L. casei*. Specification, page 19, line 10 to page 22, line 33. No knowledge of any particular epitope is required in order to use the antibodies to detect cariogenic bacteria.

The Federal Circuit's decisions in Capon and in Falkner are relevant to the instant claims.

The Federal Circuit's decision in *Capon v. Eshhar* (418 F.3d 1349, 76 USPQ2d 1078 (CAFC 2005); "*Capon*") and in *Falkner v. Inglis* (79 USPQ2d 1001 (CAFC 2006); "*Falkner*") are relevant to the instant application.

The Federal Circuit reversed the Board of Patent Appeals and Interferences finding that certain claims lacked written description, finding that the Board "erred in refusing to consider the state of the scientific knowledge".[1] The court in *Capon* stated:

> The "written description" requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same

[1] *Capon* at 1357.

> way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution....[2]

In *Falkner*, the Federal Circuit followed the *Capon* decision, and reiterated that the Office must take into account the state of the scientific knowledge.

The Federal Circuit in *Falkner* stated:

> The descriptive text needed to meet these requirements varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence. The law must be applied to each invention that enters the patent process, for each patented advance is novel in relation to the state of the science. Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science. *Id.* at 1357.
>
> As we stated in *Capon*, "[t]he 'written description' requirement states that the patentee must describe the invention; it does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution." *Id.* at 1358.

The Office Action has failed to consider the state of the scientific knowledge in the field of generating antibodies. While there may be the occasional reference describing difficulty in generating a particular antibody, the overwhelming majority of the literature indicates that the generation of antibodies is a routine matter. The Office should find, as did the Federal Circuit in *Capon* and in *Falkner*, that the specification satisfies the written description requirement of 35 U.S.C.§112, first paragraph for the claimed invention.

Given the description in the specification, including the working examples, those skilled in the art would recognize that Applicants were in possession of antibodies, as recited in claim 1, that specifically bind a cariogenic bacterium. As such, claims 1, 7, 8, 11, 12, 19, 20, 23, 24, and 26-29 are in compliance with the written description requirement of 35 U.S.C.§112, first paragraph.

Claims 1-4, 7, 8, 11, 12, 19, 20, 23, 24, and 26-29; enablement

The Office Action stated that the specification is enabling for the specific antibodies disclosed in the specification that are produced by hybridoma cell lines SWLA4 and SWLA5. The Office Action stated that the specification does not reasonably provide enablement for any other antibody that binds to any *Lactobacillus caseii* surface antigen. Applicants respectfully traverse the rejection.

[2] *Capon* at 1358.

The Office Action stated that the specification fails to describe immunoepitopes against which the claimed antibodies are raised. However, as discussed above, the instant antibodies as claimed do not require any knowledge of a specific cell surface antigen on a cariogenic bacterium. All that is required is that the antibody bind specifically to a cell surface antigen on a cariogenic bacterium. As discussed in the instant specification, an antibody that binds specifically to a cariogenic bacterium, e.g., the antibody binds almost exclusively to the specific cariogenic bacterium and not to any other cariogenic bacterium. Specification, page 4, lines 10-31.

The Office Action acknowledged that the working examples disclose specific antibodies that meet the limitations of the instant claims. The Office Action stated that the working examples "are not sufficient to provide enablement for the full scope of the rejected claims" (Office Action, page 11); however, the Office Action fails to provide a rationale as to why the working examples are not sufficient.

The instant specification describes making hybridomas to formalinized *A. naeslundii* (ATCC 12104) and *L. casei* (ATCC 11578). Specification, page 18, lines 28-29. The instant specification also describes use of an enzyme-linked immunosorbent assay (ELISA) for detecting hybridoma culture supernatants containing antibodies reactive with the corresponding bacteria. Specification, page 18, lines 30-33. The instant specification further describes how the antibodies were tested for cross-reactivity with a panel of bacteria shown in Table 1. Specification, page 19, lines 2-3; and Table 1, page 26. The instant specification then describes use of the antibodies to detect *A. naeslundii* or *L. casei*. Specification, page 19, line 10 to page 22, line 33. No knowledge of any particular epitope is required in order to use the antibodies to detect cariogenic bacteria.

The Office Action appears to insist that Applicants "fully characterize" the antigen to which the claimed antibody binds. Office Action, page 11. However, there is no requirement under 35 U.S.C. §112, first paragraph, that the antigen to which a claimed antibody binds be "fully characterized." As recited in claim 1, a claimed antibody to *Lactobacillus casei* need only be "specific for a *Lactobacillus casei* cell surface antigen **exhibits no significant cross-reactivity** with an *Actinomyces naeslundii* cell surface antigen.

Applicants have amply described how to make and how to use an antibody to *Lactobacillus casei*, where the antibody is specific for a *Lactobacillus casei* cell surface antigen exhibits no significant cross-reactivity with an *Actinomyces naeslundii* cell surface antigen. As such, the instant specification satisfies the enablement requirement under 35 U.S.C. §112, first paragraph.

Conclusion as to the rejections under 35 U.S.C. §112, first paragraph

Applicants submit that the rejections discussed above under 35 U.S.C. §112, first paragraph, has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejections.

Rejection under 35 U.S.C. §102(b) or §103(a)

Claims 1, 7, 8, 11, 19, 20, 24, and 27-29 were rejected under 35 U.S.C. §102(b) as anticipated by, or in the alternative, under 35 U.S.C. §103(a) as obvious over, Ziola et al. ((2000) *J. Am. Soc. Brew. Chem.* 58:63; "Ziola").

The Office Action stated that Ziola discloses monoclonal antibodies to *Lactobacillus* species, including *Lactobacillus casei* strain. Applicants respectfully traverse the rejection.

The Office Action pointed to Table I of Ziola to support the assertion that Ziola discloses monoclonal antibodies to *Lactobacillus* species, including *Lactobacillus casei* strain. Ziola states that monoclonal antibodies were raised to *L. casei-alactosus*. *L. casei-alactosus* is not the cariogenic bacterium *L. casei*. Furthermore, Ziola neither discloses nor suggests an antibody that specifically binds a cell surface antigen of *Lactobacillus casei*, where the antibody exhibits no significant cross-reactivity with an *Actinomyces naeslundii* cell surface antigen. As such, Ziola cannot anticipate any of claims 1, 7, 8, 11, 19, 20, 24, and 27-29.

The Office Action stated that Ziola differs from the instant invention in that Ziola does not explicitly disclose the use of colloidal labels of latex beads as a detectable label, or the packaging of the disclosed antibodies in a kit. However, as noted above, Ziola differs from the instant claims in that the bacteria to which the antibodies discussed in Ziola were raised was *L. casei-alactosus*, and not the cariogenic bacterium *L. casei*. Furthermore, as noted above, neither discloses nor suggests an antibody that specifically binds a cell surface antigen of *Lactobacillus casei*, where the antibody exhibits no significant cross-reactivity with an *Actinomyces naeslundii* cell surface antigen. There is no discussion in Ziola of any cariogenic bacteria, or of antibodies that distinguish the cariogenic bacterium *Lactobacillus casei*, from the cariogenic bacterium *Actinomyces naeslundii*. As such, Ziola cannot render obvious any of claims 1, 7, 8, 11, 19, 20, 24, and 27-29.

Conclusion as to the rejection under 35 U.S.C. §102(b) or §103(a)

Applicants submit that the rejection of claims 1, 7, 8, 11, 19, 20, 24, and 27-29 under 35 U.S.C. §102(b) or §103(a) has been adequately addressed in view of the remarks set forth above. The Examiner is thus respectfully requested to withdraw the rejection.

Rejection under 35 U.S.C. §103(a)

Claims 1, 7, 8, 11, 12, 19, 20, 23, 24, and 26-29 were rejected under 35 U.S.C. §103(a) as allegedly unpatentable over Ralls et al. (WO 00/73942; "Ralls").

The Office Action stated that Ralls discloses monoclonal antibodies to *Lactobacillus* species and the use of the antibodies in immunoassays. The Office Action stated that Ralls differs from the instant invention in that Ralls does not explicitly disclose *Lactobacillus casei* as one of the *Lactobacillus* species, nor does Ralls disclose the use of antibody fragments. The Office Action asserted that the use of *Lactobacillus casei* is an "obvious variant" of the disclosed method. Office Action, page 16. Applicants respectfully traverse the rejection.

Ralls does not disclose or suggest any antibodies that specifically bind a cell surface antigen of a *Lactobacillus* species cariogenic bacterium. Ralls provides two examples: Example 1 describes an immunoassay using polyclonal antibody to *Streptococcus mutans*; and Example 2 describes an immunoassay using polyclonal antibody to *Lactobacillus sp*. There is no specificity disclosed or discussed in Ralls. As such, Ralls cannot render obvious any of claims 1, 7, 8, 11, 12, 19, 20, 23, 24, and 26-29.

III. CONCLUSION

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number UCLA-007.

Respectfully submitted,
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Date: Dec. 18, 2007

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